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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,242	03/21/2001	Robert Haselbeck	ELITRA.011A	7191

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EXAMINER

GIBBS, TERRA C

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 03/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/815,242

Applicant(s)

HASELBECK ET AL.

Examiner

Terra C. Gibbs

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2003.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-102 is/are pending in the application.
4a) Of the above claim(s) 1-11, 13-30, 32-44 and 70 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 12, 31, 45-69 and 71-102 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date November 17, 2003.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

This Office Action is a response to Applicants Amendment and Remarks filed December 29, 2003.

Claims 1-102 are pending in the instant application.

Claims 1-11, 13-30, 32-44 and 70 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement on June 30, 2002.

This application contains claims 1-11, 13-30, 32-44 and 70 drawn to an invention nonelected with traverse on June 30, 2002. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 12, 31, 45-69 and 71-102 have been examined on the merits.

Information Disclosure Statement

Applicants Information Disclosure Statement, filed November 17, 2003 is acknowledged. The references referred to therein have been considered on the merits.

Response to Arguments

Applicants contend that claims 1-102 are pending in this application. Applicants contend that claims 1-11, 13-30, 32-44 and 70 are withdrawn without prejudice or disclaimer. Applicants

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contend that claims 12, 31, 43-69, and 70-102 are currently presented for examination. However, claims 12, 31, 43-69, and 70-102 are not currently presented for examination. Instead, claims 12, 31, 45-69 and 71-102 are presented for examination, as claims 43 and 44 are withdrawn from further consideration.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 45 and 85 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This rejection is withdrawn** in view of Applicants amendment to the claims to correct for insufficient antecedent basis.

Claims 12, 31, 45-69 and 71-102 were rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This rejection is maintained** for the reasons of record set forth in the previous Office Action, filed September 23, 2003.

In response to this rejection, Applicants argue that the instant specification provides *yphC* genes from at least six organisms, including *E. Coli*, *Haemophilus influenzae*, *Pseudomonas aeruginose*, *Streptococcus pneumoniae*, *Salmonella typhi*, and *Enterococcus faecalis*.

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Applicants contend that the instant specification provides sufficient written description to support the claims currently presented for examination.

Applicants arguments have been fully considered, but are not found persuasive because the claims currently presented for examination are broadly drawn to screening procedures accomplished by providing to a cell a sublethal level of an antisense nucleic acid which reduces the activity or amount of a gene product or by providing an antisense nucleic acid which reduces the activity or amount of a gene product, thereby producing a sensitized cell. The claims encompass a very large and highly variant genus of genes, where only seven species has been described. As argued in the previous Office Action filed September 23, 2003, the claimed invention encompasses *any gene product* in a cell whose activity is reduced by an antisense, thereby producing a sensitized cell. The Specification at age 127, Example 4, describes that, since bacterial genes are transcribed in a polycistronic manner, the antisense inhibition of a single gene in an operon might affect the expression of all the other genes on the operon or the genes downstream from the single gene identified. Therefore, the Specification as filed contemplates providing an antisense nucleic acid which reduces the activity or amount of *any gene product*, thereby producing a sensitized cell, which represents a highly variant genus, where only seven species have been identified. The skilled artisan would not be able to envision the structure of those antisense nucleic acids which reduce the activity or amount of a gene product, thereby producing a sensitized cell, based on the small number of species disclosed in the specification because the structure of such antisense nucleic acids is highly variant (e.g. nucleic acid sequence). Therefore, the full breadth of the claims does not meet the written description provision of 35 U.S.C. 112, first paragraph because the specification does not provide sufficient

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written description of an adequate number of species such that the skilled artisan would recognize that the inventors had possession of the genus of antisense nucleic acids which reduce the activity or amount of a gene product, thereby producing a sensitized cell.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is (571) 272-0758. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (571) 272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

tcg
March 18, 2004


KAREN A. LACOURCIERE,
PRIMARY EXAMINER